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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/325,214 06/03/99 NARAHARA

K M2047-3

HM22/0226

EXAMINER

NGUYEN, B

MORRISON LAW FIRM
145 NORTH FIFTH AVENUE
MOUNT VERNON NY 10550

ART UNIT

PAPER NUMBER

1641

12

DATE MAILED:

02/26/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/325,214

Applicant(s)
Narahara et al

Examiner
Bao-Thuy L. Nguyen

Group Art Unit
1641



☒ Responsive to communication(s) filed on Dec 4, 1900

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 3-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 3-8 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is confusing with respect to the description of the particles as not affecting the detection. How do these particles not affect the detection when it would appear that they bind to the detectable material and aid in their capture and retention in the catching section?

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 3-8 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cole et al (US Patent No. 5,141,850).

Cole et al disclosed a device and method for the detection of hCG, for example. The device of Cole et al includes a series of zones located on a test strip. The first zone, 18, contains a dry, reconstitutable, water-dispersible, diffusible capturable component which comprises a

second immunologically reactive substance (i.e. biotinylated 2B2 antibody). The second zone, 20, comprise the coupling product of a first immunologically reactive substance and a detectable species (i.e. gold sol labeled 2G9 antibody). The third zone, 22, comprises a capturing substance capable of interaction with the capturable component to capture and collect the capturable component at the detection zone. The capturing substance is preferably conjugated to a solid phase particle having a size in the range of 0.2μ to about 10μ (i.e. streptavidin conjugated to solid latex particles). See column 5, lines 8-24 and column 6, lines 43-48. The label of Cole et al is preferably gold sol particles having a particle size in the range from about 25 to about 1000 Å. See column 6, lines 18-20. The test strip is made of porous material having a pore size from about 5μ to about 25μ . Column 4, lines 24-30. In use, test solution is applied to the end of the test strip and chromatographically moves along the test zones by capillary action. Since the 2B2 antibody of the capturable component is reactive to a specific site on the hCG molecule, and since the 2G9 antibody of the labeled component is reactive to a different specific site on the hCG molecule, a reaction product will be formed comprising a sandwich of the labeled 2G9 component, and the hCG and the biotinylated 2B2 component. The urine with the reaction product dispersed therein will continue to diffuse and migrate along the test strip until the admixture encounters the streptavidin that is coupled to the latex particles. Reaction between the streptavidin coupled to the latex particles and the biotin coupled to the 2B2 antibody in the reaction product results in the capture and collection of the reaction product at the detection zone. If the urine sample does not contain hCG the gold labeled 2G9 antibody will simply diffuse through the detection zone and the individual gold particles will be so diffused that the distinctive coloration thereof cannot be seen. See columns 8 and 9.

Although Cole et al does not specifically state that the pore size of the detection zone (i.e. catching section) is smaller than a size of the reaction product, one of ordinary skill in the art can clearly see that such is the case. Further, it is also clear that both the latex particles and the pore size of the detection zone may be selected from the group disclosed by Cole et al to be any convenience size as desired by the operator. The selection of specific analytes is dependent on the purpose of the assay and thus the selection of any one specific analyte would have been obvious


because Cole et al teach that any appropriate test samples may be used and that their device may be adapted to test for a variety of analytes and infections.

Conclusion

5. No claim is allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy Nguyen whose telephone number is (703) 308-4243. The examiner can usually be reached Monday, Wednesday and Thursday, from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for this Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Bao-Thuy Nguyen
Patent Examiner
Group Art Unit 1641
February 25, 2001